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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,306	04/01/2004	Emanuela Keller	KELLER, E. ET AL 1	8572
25889 WILLIAM CO	7590 10/09/200 LLARD	7	EXAMINER	
COLLARD & ROE, P.C. 1077 NORTHERN BOULEVARD ROSLYN, NY 11576			LAURITZEN, AMANDA L	
			ART UNIT	PAPER NUMBER
ŕ	•		3737	
			MAIL DATE	DELIVERY MODE
			10/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)			
	10/816,306	KELLER ET AL.			
Office Action Summary	Examiner	Art Unit			
	Amanda L. Lauritzen	3737			
The MAILING DATE of this communica	ition appears on the cover sheet wit	h the correspondence address			
Period for Reply  A SHORTENED STATUTORY PERIOD FOR WHICHEVER IS LONGER, FROM THE MAI  - Extensions of time may be available under the provisions of 3 after SIX (6) MONTHS from the mailing date of this communi  - If NO period for reply is specified above, the maximum statut  - Failure to reply within the set or extended period for reply with Any reply received by the Office later than three months after earned patent term adjustment. See 37 CFR 1.704(b).	LING DATE OF THIS COMMUNIC 37 CFR 1.136(a). In no event, however, may a re cation. ory period will apply and will expire SIX (6) MONT , by statute, cause the application to become ABA	ATION. ply be timely filed I'HS from the mailing date of this communication. ANDONED (35 U.S.C. § 133).			
Status					
1) Responsive to communication(s) filed	on <i>02 April 2007</i> .				
· <u> </u>	☐ This action is non-final.				
3) Since this application is in condition for	ce this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice	under Ex parte Quayle, 1935 C.D.	11, 453 O.G. 213.			
Disposition of Claims		•			
4)⊠ Claim(s) <u>1-23</u> is/are pending in the app	olication.				
4a) Of the above claim(s) is/are					
5) Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>1-23</u> is/are rejected.					
7) Claim(s) is/are objected to.					
8) Claim(s) are subject to restriction	on and/or election requirement.				
Application Papers					
9) ☐ The specification is objected to by the E	Examiner.				
10)☐ The drawing(s) filed on is/are: a	ı)☐ accepted or b)☐ objected to b	y the Examiner.			
Applicant may not request that any objection	<del>-</del>	• •			
Replacement drawing sheet(s) including th	•				
11)☐ The oath or declaration is objected to b	y the Examiner. Note the attached	Oπice Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
12)⊠ Acknowledgment is made of a claim for a)⊠ All b)□ Some * c)□ None of:		119(a)-(d) or (f).			
1. Certified copies of the priority do					
	ocuments have been received in Ap				
	the priority documents have been	received in this National Stage			
application from the Internationa	• • • • • • • • • • • • • • • • • • • •	roppiyad			
* See the attached detailed Office action f	for a list of the certified copies not i	eceived.			
Attachment(s)  1) Notice of References Cited (PTO-892)	4) Intension S	ummary (PTO-413)			
<ul> <li>2) Notice of References Cited (PTO-092)</li> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-092)</li> </ul>		)/Mail Date			

Paper No(s)/Mail Date \_\_

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)

5) Notice of Informal Patent Application

6) Other: \_\_\_\_

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## Response to Arguments

Applicant's arguments with respect to claims 1 and 13 have been considered but are moot in view of the new ground(s) of rejection. Applicant now specifies that an input signal is divided into pulsatile and nonpulsatile components. Chen US 6,339,714 (of record) is now applied for teaching this feature.

#### **DETAILED ACTION**

#### **Priority**

1. Applicant's claim for the benefit of a prior-filed German Application No. 103 15 574.0 filed Apr. 5, 2003 is acknowledged under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c).

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 1, 2, 4, 7-9, 11-16 and 19-20 rejected under 35 U.S.C. 103(a) as being unpatentable over Pfeiffer et al. (US 6,233,069) in view of Chen (US 6,339,714).

Pfeiffer et al. disclose a device for measuring cerebral blood flow using an injection of indocyanine green as an indicator for near infrared spectroscopy (abstract; col. 2, lines 6-7). The method and Pfeiffer is specific to emitting and detecting radiation at first and second locations, respectively (see measurement through both brain hemispheres cited at col. 2, lines 44-45). The arterial dye curve and cerebral dye curve are taken to be inflow and outflow functions as defined

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by applicant and inherently correspond to non-pulsatile and pulsatile components of the signal (see arterial and cerebral curves at col. 5, lines 1-10). The optical density is monitored to determine an inflow function according to the change in dye concentration with respect to time (effectively the derivative) in the tissue (col. 4, lines 34-37). The convolution integral defines an outflow function (col. 5, line 10). The mean transit time is specified in determination of the inflow function and "varying rates" imply variation of transit times (col. 5, lines 40-49). The process of determining the inflow function is deemed iterative (col. 5, line 19). Pfeiffer et al. disclose using blood flow and mean transit time to determine the volume (col. 8, lines 13-15), with a flow parameter by definition being a quotient of volume and time (col. 5, line 33 for ml/min for a flow transport function). The auxiliary variable of the integral provides a scaling factor (col. 5, lines 10-11). The method of Pfeiffer includes an iterative determination of the inflow function that is represented as a sum of a finite number of functions that are similar in form to the transport function (col. 5, lines 38 for the transport function and line 52 for the summation).

Pfeiffer et al. disclose all features of the invention as substantially claimed, as detailed above, but do not delineate that the signal is divided into pulsatile and nonpulsatile components; however, in the same field of endeavor, Chen teaches a method for estimating cerebral blood flow using near infrared spectroscopy and Indocyanine green as an indicator, in which the pulsatile and nonpulsatile components are divided (col. 3, lines 8-14). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate this feature for the purpose of obtaining the attenuation purely due to arterial blood (col. 3, lines 13-14).

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3. Claims 3, 5, 6, 10, 17, 18 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfeiffer '069 in view of Chen'714, further in view of Boas (U.S. 6,516,214).

Pfeiffer as appended by Chen includes all features of the invention as substantially claimed but is silent with regard to the steps of using a threshold value, extrapolation of a scaled inflow function, and applying a locally increased contact pressure, but in the same field of endeavor, Boas discloses establishing a threshold for dye concentration comparison (col. 3, lines 2-7), extrapolating the position from the scaled inflow function for determining the location of an ischemic event (col. 3, lines 27-39), and applying contact pressure (see flexible cap 400 with rubber grommets 440 that generates pressure in order to fix the device to the patient's scalp; also col. 10, lines 20-42). It would have been obvious to one of ordinary skill in the art at the time of invention to include the steps of using a threshold value for comparison purposes and extrapolation of data for determining location as taught by Boas with the method of Pfeiffer in order to evaluate an ischemic event (abstract; also col. 3, lines 13-14).

### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda L. Lauritzen whose telephone number is (571) 272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALL 10/1/2007

E.L. L. BOLA MARKE ENVIOUR